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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/606,618	JUDD ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,25,30-37,39-46 and 50-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 25, 30-37, 39-46 and 50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 09/21/06 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 09/21/06 in response to the final Office Action mailed 05/08/06.

Status of Claims

3) Claims 38, 47-49, 53 and 54 have been canceled via the amendment filed 09/21/06.

Claims 21, 25, 32, 34-37, 39, 42-46 and 50-52 have been amended via the amendment filed 09/21/06.

Claims 21, 25, 30-37, 39-46 and 50-52 are pending and are under examination.

Terminal Disclaimer

4) Acknowledgment is made of Applicants' terminal disclaimer filed 09/21/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 6,610,306.

Prior Citation of Title 35 Sections

5) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

6) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

7) The rejection of claim 38 made in paragraph 33 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of

Applicants' cancellation of the claim.

8) The rejection of claim 53 made in paragraph 38 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claim.

9) The rejection of claim 53 made in paragraphs 39(b), 39(f), 39(j), 39(k) and 39(n) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

10) The rejection of claim 38 made in paragraph 39(g) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claim 38 made in paragraph 43 of the Office Action mailed 05/08/06 under 35 U.S.C § 102(e)(2) as being anticipated by Rubenfield *et al.* (US 6,551,795, filed 02/18/1998), is moot in light of Applicants' cancellation of the claim.

12) The rejection of claim 38 made in paragraph 44 of the Office Action mailed 05/08/06 under 35 U.S.C § 102(b) as being anticipated by Manning *et al.* (*Microb. Pathogenesis*. 25: 11-22, July 1998, already of record) (Manning *et al.*, 1998) in light of Richarme *et al.* (*Ann. Microbiol.* 133A: 199-204, 1982, already of record), is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

13) The rejection of claim 21 made in paragraph 9 of the Office Action mailed 08/05/05 and maintained in paragraph 30 of the Office Action mailed 05/08/06 under the judicially created doctrine of obviousness-type double patenting over claim 1 of the US patent 6,610,306, is withdrawn in light of Applicants' submission of the terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 6,610,306.

14) The rejection of claims 50, 30 and 31 made in paragraph 31 of the Office Action mailed 05/08/06 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 2 of the US patent 6,610,306, is withdrawn in light of Applicants' submission of the

terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US patent 6,610,306.

15) The rejection of claim 21 and those dependent therefrom made in paragraph 32 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claim 25 made in paragraph 33 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 39 made in paragraph 34 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claims 30, 31, 40 and 41 and those dependent therefrom made in paragraph 35 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn.

19) The rejection of claims 32, 33 and 42 made in paragraph 36 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn upon further consideration.

20) The rejection of claims 34-36 and 44-46 made in paragraph 37 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claims.

21) The rejection of claims 50-52 made in paragraph 38 of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the base claim.

22) The rejection of claims 21, 25 and 50 made in paragraph 39(a) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

23) The rejection of claim 51 made in paragraph 39(b) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.

24) The rejection of claim 25 made in paragraph 39(c) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.

25) The rejection of claims 32-36, 42 and 44 made in paragraph 39(d) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

26) The rejection of claims 34 and 44 made in paragraph 39(e) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

27) The rejection of claims 37, 43 and 50 made in paragraph 39(f) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

28) The rejection of claims 25 and 39 made in paragraph 39(h) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn upon further consideration.

29) The rejection of claims 34 and 44 made in paragraph 39(i) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn upon further consideration.

30) The rejection of claims 30-46 and 51-52 made in paragraph 39(n) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn

31) The rejection of claims 35 and 45 made in paragraph 39(l) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

32) The rejection of claim 52 made in paragraph 39(m) of the Office Action mailed 05/08/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

33) The rejection of claims 21, 25, 30-36, 39-42, 44-46, 50 and 52 made in paragraph 42 of the Office Action mailed 05/08/06 under 35 U.S.C. § 102(b) as being anticipated by Wetzler *et al.* (*J. Exp.*

Med. 169: 2199-2210, 1989) as evidenced by Hunter (US 5,554,372) or Berinstein *et al.* (US 20040033234) and Harlow *et al.* (*In*: *Antibodies: A Laboratory Manual.* Cold Spring Harbor Laboratory, New York, pages 471-510, 1988), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

34) The rejection of claims 21, 25, 30-37, 39 and 40-46 made in paragraph 43 of the Office Action mailed 05/08/06 under 35 U.S.C § 102(e)(2) as being anticipated by Rubenfield *et al.* (US 6,551,795, filed 02/18/1998), is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s). A modified rejection is set forth below addressing the claims as amended.

35) The rejection of claims 21, 25, 30-37, 39 and 40-46 made in paragraph 44 of the Office Action mailed 05/08/06 under 35 U.S.C § 102(b) as being anticipated by Manning *et al.* (*Microb. Pathogenesis.* 25: 11-22, July 1998, already of record) (Manning *et al.*, 1998) in light of Richarme *et al.* (*Ann. Microbiol.* 133A: 199-204, 1982, already of record), is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s). A modified rejection is set forth below addressing the claims as amended. Applicants should note that the previously filed *Katz* declaration does not overcome a 35 U.S.C §102(b) rejection.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

36) Claims 21, 50 and those dependent therefrom are rejected under 35 U.S.C § first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 21 and 50, as amended, include the limitations: 'said polypeptide isolatable from *Neisseria* bacteria, and wherein ..... said composition induces antibodies in a mammalian patient that bind to said amino acid sequence of SEQ ID NO: 4 on the surface of said *Neisseria* bacteria and that interfere with the ability of said bacteria to adhere to mammalian cells'. Claim 25, as amended, includes the new limitation: 'isolatable from *Neisseria* bacteria'. For the new limitation 'isolatable from *Neisseria* bacteria', Applicants point for support to page 11, line 29 to page 12, lines 1-11 and lines 26-28; lines 10-12 of page 13; page 18, line 28 to page 19, line 11; and Examples 2 and 3. However, page 11, line 29 to page 12, lines 1-11 and lines 26-28 and

lines 10-12 of page 13 of the instant specification do not describe an immunogenic composition comprising an isolated polypeptide comprising at least eight consecutive amino acids from SEQ ID NO: 4, wherein the polypeptide is 'isolatable' from any generic *Neisseria* bacteria. These parts of the specification describe a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 isolated from *N. meningitidis* and/or a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 isolated from *N. gonorrhoeae*. No generic *Neisseria* from which an eight amino acid-long polypeptide of SEQ ID NO: 4 is isolatable are described herein. Page 18, line 28 to page 19, line 11 of the specification do not describe any generic *Neisseria* from which an eight amino acid-long polypeptide of SEQ ID NO: 4 is isolatable. Example 2 is limited to cloning and immunological screening of a genomic gonococcal library and encoding of SEQ ID NO: 2 by a gonococcus. Example 3 is limited to cloning and sequencing of meningococcal OMP85, i.e., SEQ ID NO: 4. These two examples do not describe any non-meningococcal or non-gonococcal generic *Neisseria* from which an eight amino acid-long polypeptide of SEQ ID NO: 4 is isolatable. For the new limitations in the claims: 'said composition induces antibodies in a mammalian patient that bind to said amino acid sequence of SEQ ID NO: 4 on the surface of said *Neisseria* bacteria and that interfere with the ability of said bacteria to adhere to mammalian cells', Applicants point to lines 26-29 of page 20; lines 25-30 of page 25; page 26, line 14 to page 27, line 2; page 35, lines 7-10; and Example 8 on page 53 for support. These parts of the specification however do not describe an at least eight amino acid-long polypeptide from SEQ ID NO: 4 isolatable from any *Neisseria,* which eight amino acid-long polypeptide induces antibodies in a 'mammalian patient' that bind to said amino acid sequence of SEQ ID NO: 4 on the surface of said '*Neisseria*' bacteria and that interfere with the ability of said bacteria to adhere to 'mammalian cells'. The limitation 'mammalian patient' is new matter. The term '*Neisseria*' encompasses non-pathogenic commensal *Neisseria* that do not cause infection in a mammalian patient. The amino acid sequence of SEQ ID NO: 4 being present on the surface of any commensal *Neisseria* such that the antibodies induced by an eight amino acid-long polypeptide from SEQ ID NO: 4 can bind to and interfere with the ability of these commensal *Neisseria* or the ability of *Neisseria gonorrhoeae* to adhere to any generic mammalian cells, is not described in these parts of the specification. Example 8 is limited to 'gonococcal cell adherence assay' that specifically uses Chang epithelial or conjunctiva cells. The antiserum used

is the one prepared to the first 178 amino acids of gonococcal Omp85 having the amino acid sequence of SEQ ID NO: 2. Example 8 is limited to a description of this anti-gonococcal Omp85 antiserum binding to the surface of gonococci and interfering with the ability of gonococci to adhere specifically to the Chang epithelial cells. This does not provide descriptive support to the new generic limitations identified above. The description of Chang epithelial cell species does not provide support for the newly recited genus of 'mammalian cells', since mammalian cell genus encompasses cells other than Chang epithelial cells. The antibodies that interfered with the ability of gonococci to adhere to the Chang epithelial cells were induced by a polypeptide consisting of the first 178 amino acids of SEQ ID NO: 2, and not by an eight amino acid-long polypeptide from SEQ ID NO: 4. The first 178 amino acids of SEQ ID NO: 4 and SEQ ID NO: 2 are non-identical in structure or amino acid composition (see Figure 5). Similar rejection and analysis applies to claim 50, wherein the polypeptide comprising an amino acid sequence having 95% or greater sequence identity induces antibodies in a 'mammalian patient' that bind to said amino acid sequence of SEQ ID NO: 4 on the surface of said '*Neisseria*' bacteria and that interfere with the ability of said bacteria to adhere to 'mammalian cells'. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

37) Claim 34 and those dependent therefrom are rejected under 35 U.S.C § first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 34, as amended, includes the new limitations: said antibodies also recognize protein in multiple '*Neisseria gonorrhoae* strains and *Neisseria meningitidis* strains, said proteins appearing as reactive bands approximately 85 kD on a Western blot'. Applicants point to page

52, line 29 through page 53, line 7; and Figure 6 for support for the new limitations. However, these parts of the specification do not provide support for the claim as now amended. The antibodies that recognize proteins from *Neisseria gonorrhoae* strains FA19, FA635, FA1090, JS1, F62 and MS11LosA, and *Neisseria meningitidis* strains MP78, MP3, MP81 and HH were produced as described in Example 7 (see Figure 6 description on page 10). The antisera described in Example 7 are polyvalent rabbit sera produced through the use of a fusion protein in which the first 200 amino acids of the gonococcal Omp85 (SEQ ID NO: 2) were genetically fused to MBP. These antibodies were not induced by an eight amino acid-long polypeptide from SEQ ID NO: 4, as now claimed in the dependent claim 34. The first 200 amino acids of SEQ ID NO: 4 and SEQ ID NO: 2 are non-identical in structure or amino acid composition (see Figure 5). Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

38) Claims 43 and 51 are rejected under 35 U.S.C § first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Dependent claims 43 and 51, as amended, continue to include the limitations: said polypeptide lacks a signal sequence spanning amino acids 1-21 of said amino acid sequence of SEQ ID NO: 4. Applicants state that one of skill in the art would understand that the signal sequence identified in FIG. 2 for SEQ ID NO: 2 is identical and in the identical position in the homologous OMP85 protein of SEQ ID NO: 4. Applicants submit that the identification of that signal sequence and cleavage site in SEQ ID NO: 2 is 'inherent for the same sequence and cleavage site in SEQ ID NO: 4'. Applicants conclude that one of skill in the art, given the

present disclosure, would find inherent support for the claim language of claims 43 and 51. The limitations 'said polypeptide lacks signal sequence spanning amino acids 1-21 of said amino acid sequence of SEQ ID NO: 4' constitute new matter for the following reasons. As is evident from Figure 5, the amino acid sequences of SEQ ID NO: 4 is non-identical to the amino acid sequence of SEQ ID NO: 2 in amino acid composition and length. The amino acid sequence of SEQ ID NO: 4 is 797 amino acids in length, whereas the amino acid sequence of SEQ ID NO: 2 is 792 amino acids in length. More than 30 amino acid residues are different in these two sequences. See Figure 5. The signal peptide that is identified in Figure 2 is for the gonococcal Omp85 having the amino acid sequence of SEQ ID NO: 2, not for the structurally distinct meningococcal Omp85 having the amino acid sequence of SEQ ID NO: 4. The figure 2 descriptions are limited to SEQ ID NO: 2. The reference recited therein of von Heijne (*Nucl. Acids Res.* 14: 4683-4690, 1986) does not identify the signal peptide of an at least eight consecutive amino acid-containing polypeptide from SEQ ID NO: 4, or an amino acid sequence having 95% or greater sequence identity with SEQ ID NO: 4, or of any gonococcal, meningococcal, or neisserial polypeptide to be spanning amino acids 1-21 of SEQ ID NO: 4. Contrary to Applicants' argument set forth on page 11 of their response filed 09/21/06, the identification of the signal sequence and cleavage site in SEQ ID NO: 2 does not inherently support the same signal sequence and cleavage site in the structurally distinct and much longer SEQ ID NO: 4. No part of the specification provides the descriptive support for the eight amino acid-long diagnostic polypeptide from SEQ ID NO: 4 lacking 1-21 amino acids of SEQ ID NO: 4 as now recited in claim 43 which is isolatable from any generic *Neisseria* and is associated with a suitable detectable label. No part of the specification provides the descriptive support for an immunogenic polypeptide comprising an amino acid sequence having 95% or greater sequence identity with SEQ ID NO: 4 lacking 1-21 amino acids of SEQ ID NO: 4 as now recited in claim 51, which signal peptide-lacking polypeptide induces antibodies in a mammalian patient that bind to SEQ ID NO: 4 on the surface of any generic *Neisseria* and that interfere with the ability of said *Neisseria* to adhere to generic mammalian cells. Note that the antibodies were produced using the first 178 amino acids of SEQ ID NO: 2 (see Example 8) which *includes* the signal peptide and which is non-identical in amino acid composition to the first 178 amino acids of SEQ ID NO: 4. The antibodies described in Example 7 were produced using the first 200 amino acids of the gonococcal SEQ ID NO: 2

which *includes* the signal peptide and which is non-identical in amino acid composition to the first 200 amino acids of SEQ ID NO: 4. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

39) Claims 21, 25-37, 39-46 and 50-52 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 21 is incorrect in the redundant limitations: 'said said' (line 7).

(b) Claim 21 is indefinite in the limitation: '*Neisseria* bacteria'. Since *Neisseria* are inherently bacteria and not viruses or fungi, it is suggested that Applicants delete the limitation 'bacteria' from lines 6 and 9, and replace the limitation 'said bacteria' at the end of line 9 with the limitation --said *Neisseria*--.

(c) Analogous criticism and rejection applies to claims 25 and 50 with regard to the limitation: '*Neisseria* bacteria' therein.

(d) Claim 34, as amended, has improper antecedent basis in the limitation: 'said proteins' (see line 3), because the earlier limitation in line 2 of the claim is of 'protein', not of 'proteins'.

Rejection(s) under 35 U.S.C § 102

40) Claims 21, 25, 30-37 and 39-46 are rejected under 35 U.S.C § 102(e)(2) as being anticipated by Rubenfield *et al.* (US 6,551,795, filed 02/18/1998, already of record) as evidenced by Harlow *et al.* (*In*: *Antibodies: A Laboratory Manual*. Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988, already of record).

The transitional limitations 'having', 'comprising', 'including', 'containing', or

'characterized by', represent open-ended claim language and therefore, do not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). Therefore, the limitation 'comprising' or 'contains' in the instant claim(s) allows additional amino acid residues to be present on one or either side of the recited polypeptide, or a fragment or peptide fragment thereof. It should be noted that the transitional phrase 'consisting of' excludes any element, step, or ingredient not specified in the claim. *In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('consisting of' defined as 'closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.').

Rubenfield *et al.* disclosed an isolated or substantially pure 648 amino acid-long polypeptide having the amino acid sequence of SEQ ID NO: 24628 comprising the eight consecutive amino acids, VRVETADG, which eight consecutive amino acids are identical to the eight amino acid-long fragment, VRVETADG, located at amino acid positions 74 through 81 of the instantly recited SEQ ID NO: 4. A therapeutic or prophylactic vaccine comprising the polypeptide and a pharmaceutically acceptable carrier as well as a diagnostic composition, a diagnostic reagent capable of providing a detectable signal comprising the polypeptide modified with a label, such as a radioisotope or a fluorescent label, is taught. A diagnostic kit comprising the polypeptide being present on immobilization means such as particles, supports (inclusive of latex), wells, dipsticks, and the nitrocellulose papers containing the polypeptide, is also disclosed. The polypeptide exists as a recombinant fusion protein fused to a polyhistidine sequence, i.e., fused to a second heterologous protein or polypeptide. The polypeptide is co-administered with an adjuvant. The polypeptide does not contain amino acids 1-21 of the instantly recited SEQ ID NO: 4. See sequence alignment report attached to the Office Action mailed 05/08/06; and Sequence Listing; third full paragraph in column 5; first three paragraphs in column 6; lines 18-29 in column 11; and 'Vaccine Formulations for P. aeruginosa .... Polypeptides' in columns 37-40; section 'Kits Containing ... Polypeptides of the Invention'; and lines 1-5 in column 42. Since the isolated prior art polypeptide is not fully purified, it is

expected to inherently contain at least a second *P. aeruginosa* protein or polypeptide contaminant, i.e., second polypeptide or protein antigen from a pathogenic species heterologous to *Neisseria meningitidis* or *Neisseria gonorrhoeae*. That the prior art 8 amino acid-long polypeptide induces antibodies which bind to the instant polypeptide of SEQ ID NO: 4 on the surface of *Neisseria* as recited in the instant claims is inherent from the teachings of the prior art, since such a polypeptide is well known in the art to be long enough to elicit an antibody response in a mammalian patient. The art recognizes that the smallest peptides that elicit antibodies which bind to the original full-length protein are 6 amino acids in length. See first sentence under 'Size of the Peptide' on page 76 of Harlow *et al.* Furthermore, although Rubenfield *et al.* are silent about the ability of their eight consecutive amino acid-containing polypeptide to induce antibodies in a mammalian patient that bind to the amino acid sequence of SEQ ID NO: 4 as recited in the instant claims, the prior art polypeptide is viewed as the same as the Applicants' polypeptide because of the identical structural composition. In spite of the fact that the prior art fails to teach all of the disclosed functional characteristics of the Applicants' polypeptide, there is total structural overlap to reasonably conclude that the prior art eight consecutive amino acid-containing polypeptide is one and the same as the Applicants' eight consecutive amino acid-containing polypeptide. Since the prior art eight consecutive amino acid-containing polypeptide is structurally the same as the polypeptide recited in the instant claims, it is expected to have the same intrinsic binding and adherence-interfering properties as that of the Applicants' polypeptide.

The teachings of Rubenfield *et al.* anticipate the instant claims. Harlow *et al.* is **not** used as a secondary reference in combination with Rubenfield *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Rubenfield *et al.* with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

The limitation 'isolatable from *Neisseria* bacteria' in the instant claims is viewed as a process limitation in product claims. It should be noted that when claims are drawn to a product-by-process, claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps. MPEP § 2113 states:

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

> production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)* (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the isolation process results in a product that is structurally different from the product of the prior art.

41) Claims 21, 25, 31-36, 39-42, 44-46, 50, 52 and 53 are rejected under 35 U.S.C § 102(b) as being anticipated by Manning *et al.* (*Microb. Pathogenesis.* 25: 11-22, July 1998, already of record) (Manning *et al.*, 1998) in light of Richarme *et al.* (*Ann. Microbiol.* 133A: 199-204, 1982, already of record).

Because of the new matter identified above, the instant claims are granted the effective filing date of the instant application, i.e., 06/26/03.

It is noted that the authorship of Manning *et al.* (1998) and the inventorship of the instant application are non-identical.

Manning *et al.* (1998) taught an isolated outer membrane protein (i.e., Omp85 polypeptide) of *N. meningitidis* comprising the 797 amino acid-long amino acid sequence with the Genebank accession No. AF021245 that has 100% sequence identity with the instantly recited SEQ ID NO. 4 of the instant invention. Manning's protein comprises at least eight consecutive amino acid residues of the instantly recited SEQ ID NO: 4. See especially Figure 5 and abstract of Manning *et al.* (1998); and the sequence search report attached to the Office Action mailed 08/05/05. The protein taught by Manning *et al.* (1998) is a recombinant protein, or a fusion protein fused to a second polypeptide such as MBP or maltose binding protein. See page 15; 'Materials and Methods'; and page 20 under 'Production of a MBP/Omp85 fusion protein'. A composition (i.e., immunogenic composition) comprising 0.1 to 1.0 mg of the purified MBP/Omp85 contained in an adjuvant (i.e., pharmaceutically acceptable carrier) for use in an immunization procedure is taught. See page 20, right column, first full paragraph. The Neisserial Omp85 proteins are believed to be important immunological targets of the host immune response (see first paragraph under 'Conclusions'). Manning *et al.* (1998) taught that the meningococcal Omp85 protein is 95% identical to the gonococcal Omp85 (see page 15, left column; and Figure 2), and thus Manning *et al.* (1998) taught a homologue polypeptide of the

instantly recited SEQ ID NO: 4 that has at least 95% identity to SEQ ID NO: 4 or that contains conservative amino acid amino acid replacements as recited. Manning *et al.* (1998) further taught that Omp85 homologues are identified in all of the commensal neisserial species tested and that the Omp85 protein is conserved among all the neisserial species (see paragraph bridging pages 15 and 16; and Figure 6), thus indicating the inherent ability of the prior art polypeptide to induce antibodies cross-reactive with multiple *Neisseriae* strains. Although Manning *et al.* are silent about the ability of their eight consecutive amino acid-containing polypeptide to induce antibodies in a mammalian patient that bind to the amino acid sequence of SEQ ID NO: 4 as recited in the instant claims, the prior art polypeptide is viewed as the same as the Applicants' polypeptide because of the identical structural composition. In spite of the fact that the prior art fails to teach all of the disclosed functional characteristics of the Applicants' polypeptide, there is total structural overlap to reasonably conclude that the prior art eight consecutive amino acid-containing polypeptide is one and the same as the Applicants' eight consecutive amino acid-containing polypeptide. Since the prior art eight consecutive amino acid-containing polypeptide is structurally the same as the polypeptide recited in the instant claims, it is expected to have the same intrinsic binding and adherence-interfering properties as that of the Applicants' polypeptide. That maltose binding protein fusion partner taught by Manning *et al.* is an antigen from a heterologous pathogenic species is inherent from the teaching of Manning *et al.* in light of what is well known in the state of the art. For instance, Richarme *et al.* taught the source of maltose binding protein to be *E. coli* bacteria see abstract). The polypeptide induced anti-Omp85 antisera in rabbits which recognized the Omp85 polypeptide in *N. meningitidis* strains HH, MP78, MP3 and MP81 and *N. gonorrhoeae* strains FA19, FA635, FA1090, JS 1, MS 11 and F62 by the diagnostic Western blot analysis that used PVDF membrane (see Figure 6 and 7). The limitation 'diagnostic kit' is viewed as representing the intended use of the claimed product and is not given any patentable weight.

The teachings of Manning *et al.* anticipate the instant claims. Richarme *et al.* is not used as a secondary reference in combination with Manning *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Manning *et al.*, because Richarme *et al.* teach maltose binding protein to be of *E. coli* (heterologous species) origin. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Claims 21, 25, 31-36, 39-42, 44-46, 50 and 52 are anticipated by Manning *et al.*

Remarks

42) Claims 21, 25, 30-37, 39-46 and 50-52 stand rejected.

43) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives facsimile transmissions 24 hours a day and 7 days a week.

44) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

45) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-1600.

December, 2006

S. DEVI, PH.D.
PRIMARY EXAMINER